THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CLAUDIUS KORMANN, MICHEL R. ANSEAU AND ROBERT N. MULLER

> Appeal No. 1997-2199 Application No. 08/369,340

> > _____

ON BRIEF

Before OWENS, WALTZ, and LIEBERMAN, <u>Administrative Patent Judges</u>. LIEBERMAN, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 1 and 20 which are all the claims pending in the application.

THE INVENTION

The invention is directed to an MRI contrasting medium consisting essentially of an aqueous dispersion of super paramagnetic solid particles, and a polyelectrolyte. The super paramagnetic particles have a particle size of 7-50 nm, a surface area of 30-

130 m²/g and are present in a dispersion in the form of colloidal units. The polyelectrolyte has a molecular weight of 1,000 to 25,000 and has a charge number of at least 5.0. Moreover, the relaxivities of the contrast media are such that r_1 is greater than

9 x 10^4 M⁻¹s⁻¹ and the ratio of r_2 is at least 7 under specified conditions.

THE CLAIMS

Claims 1 is illustrative of appellants' invention and is reproduced below.

1. A dual purpose MRI contrast medium consisting essentially of an aqueous dispersion of superparamagnetic solid particles and at least one polyelectrolyte which acts as a dispersant, said polyelectrolyte having an average molecular weight of from 1,000 to 25,000, said superparamagnetic solid particles having a primary particle size of from 7 to 50 nm and a specific surface area of from 30 to 130 m²/g and being present in the dispersions in the form of colloidal units with on average only one superparamagnetic solid particle enveloped by the polyelectrolyte, and said polyelectrolyte having a charge number greater than 5, with the proviso that the relaxivities of the contrast media are such that r_1 is greater than 9 x 10^4 M¹s¹¹ and the ratio of r_2 to r_1 is at least 7, measured at 20 MHz and 37° C.

As evidence of obviousness, the examiner relies upon the following references.

 Groman et al.
 4,827,945
 May 9, 1989

 Pil grimm
 5,160,725
 Nov. 3, 1992

 kl aveness et al.
 W0 89/11873
 Dec. 14, 1989

THE REJECTION

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Klaveness, Pilgrimm and Groman.

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with the appellants that the aforementioned rejections under 35 U.S.C. § 102 and U.S.C. § 103 are not well founded. Accordingly, we do not sustain the examiner's rejections.

The Rejection under Section 102--Anticipation

In order for a claimed invention to be anticipated under 35 U.S.C. § 102(b), all of the elements of the claim must be found in one reference. See <u>Scripps Clinic & Research Found. v. Genentech Inc.</u>, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

The examiner appears to rely upon a combination of three references to reject the claims on the grounds of anticipation. That rejection and its reliance on three combined references is clearly improper. As for consideration of each reference individually, the examiner concedes that the references, "do not specifically set forth all of the claimed designated functional limitations." See Answer, page 4. Functional limitations as exemplified by the particle size, specific surface area, and the colloidal state of the superparamagnetic particles, the molecular weight and charge number of the polyelectrolyte are elements of the claim which must be all present in a single reference. The examiner's position is that the references are presumed to contain,

"all of said functional limitation and, as such anticipate the claim designated invention."

However, the burden of proof rests with the examiner to establish *a prima facie*case of anticipation. We determine that none of the references teach each of the elements required by the claimed subject matter. Accordingly, we reverse the rejection on the grounds of anticipation.

The Rejection under Section 103--Obviousness

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The examiner relies upon a combination of three references to reject the claimed subject matter and establish a *prima facie* case of obviousness. The premises of the rejection are that in the event that appellants show that the references do not inherently contain the designated functional limitations of the claimed subject matter, "it would have been obvious to those of ordinary skill in the art that minor variations in the relaxivity, molecular weight size, etc. could be made so as to produce the most suitable composition for magnetic resonance imaging." See Answer, page 4. We disagree.

In our view, not only does each of the references fail to teach the requisite relaxivities of the claimed subject matter, they fail to teach an MRI contrast medium having the requisite claimed characteristics that would result in obtaining the relaxivities of the claimed subject matter.

We find that Klaveness is directed MRI containing super paramagnetic particles and a chelating agent. See Abstract. Chelating agents are disclosed. See page 7, and especially pages 8 and 9. However, there is nothing to show that any of the chelating

agents have either the requisite molecular weight or charge number. We further find that the magnetic particles have the requisite particle size 5-50nm. See page 10. However, no surface area is disclosed. Furthermore, the specific examples do not disclose the requisite combination of molecular weight and charge number.

We find that Groman discloses super paramagnetic oxides as MR imaging agents which may be surrounded by a polymeric coating. See Abstract. The super paramagnetic particles have the requisite particle size and surface area. See column 8, lines 1-4. See also column 10, line 67 to column 11, line 4. Stable super paramagnetic fluids may be prepared by coating the metal oxides with polymeric substances. See column 16,

lines 1-24. However, the examiner has not shown that these polymeric substances meet the requirements of the claimed subject matter.

We further find that Pilgrimm discloses a magnetic liquid composition containing aqueous dispersions of stabilized super paramagnetic particles chemically bonded to phosphate, phosphonate or carboxylate groups. Both particle size and surface area are disclosed at column 3, lines 8-10. The stabilizer substances to which the magnetic particles are bonded are taught at column 3, lines 33-38. For aqueous, magnetic liquid compositions the stabilizers appear to be taught at column 3, lines 60 to column 4, line 30 and include polymethacrylic or polyacrylic acid. However, no molecular weight for the polymethacrylic acid or polyacrylic acid is disclosed.

Based upon the above findings and analysis, we determine that none of the references taken alone or together suggest or teach all of the claimed compositional limitations, let alone the derived relaxivity limitations of the claimed

subject matter. Although relaxivity may inherently be present, provided that all other limitations are also present, inherency requires that the characteristic must necessarily be present. It may not be established by probabilities or possibilities. Hence, the mere possibility that polymethacrylic acid or polyacrylic acid may be present in the disclosure of Pilgrimm is not sufficient to establish inherency. See <u>In re Oelrich</u>, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); <u>Ex parte</u> <u>Skinner</u>, 2 USPQ2d 1788, 1789 (Bd. Pat. App. & Int. 1986). Furthermore, the examiner must provide some evidence or scientific reasoning that the presence of the "relaxivity" characteristic is an inherent characteristic of the prior art compositions. In the case before us no such evidence or reasoning has been set forth.

Accordingly, the rejection of the examiner is reversed.

DECISION

The rejection of claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Klaveness, Pilgrimm and Groman is reversed.

The decision of the examiner is reversed.

REVERSED



Appeal No. 1997-2199 Application No. 08/369,340

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Appeal No. 1997-2199 Application No. 08/369,340

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DECISION: REVERSED Send Reference(s): Yes No or Translation (s) Panel Change: Yes No Index Sheet-2901 Rejection(s):

Prepared: July 13, 2001

Draft Final

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OB/HD GAU

PALM / ACTS 2 / BOOK DISK (FOIA) / REPORT